

Passion for Innovation.  
Compassion for Patients.™



# ENHERTU® Business Briefing

**DAIICHI SANKYO CO., LTD.**

**March 21, 22 2024**

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# Presenters



**Sunao Manabe**  
Executive Chairperson and CEO



**Ken Keller**  
Head of Oncology Business Unit

ENHERTU®

# Business Briefing

# Ken Keller

*Global Head, Oncology Business  
President & CEO, Daiichi Sankyo, Inc.*

- Joined Daiichi Sankyo in 2014
- Revamped U.S. business structure to focus on multiple oncology launches including ENHERTU® as part of Daiichi Sankyo's 2025 Goal
- More than 30 years of experience in the pharmaceutical industry including 22 years at Amgen
- Held senior regional and global leadership roles supporting major biologics including Aranesp, Enbrel, Neulasta, Neupogen, Prolia, Vectibix, and Xgeva



# Transforming into a Global Oncology Leader

**ENHERTU<sup>®</sup>  
revenue >  
\$2.5B per  
annum**

**Strong commercial  
execution across the  
globe**

- ENHERTU<sup>®</sup> has achieved the leadership position in all 4 indications in every country/region it has been fully launched in
- Delivering continued growth in “early launch” countries/regions and accelerated growth rates in “later launched” countries/regions

**Multiple new  
ENHERTU<sup>®</sup> growth  
catalyst expected  
in the near term**

- Tumor Agnostic indication under FDA review
- Large patient populations with high unmet need would benefit from earlier use of ENHERTU<sup>®</sup> (DESTINY-Breast06 and DESTINY-Breast09)

**Expanding  
Oncology  
portfolio**









- HER3-DXd submitted and accepted for FDA review
  - EGFRm NSCLC 3L
- Dato-DXd submitted and accepted for review\*
  - Non-sq mNSCLC 2L and HR+/HER2 low or negative mBC

**Global  
Oncology  
Business  
foundation  
established  
and ready  
to optimize  
future growth  
opportunities**

\* BLA submitted and accepted by FDA for 2L mNSCLC; MAA also submitted in European Union for patients with advanced non-squamous non-small cell lung cancer or HR positive, HER2 low or negative metastatic breast cancer  
BC, breast cancer; HR, hormone receptor; NSCLC, non-small cell lung cancer; Non-sq: non-squamous

# Strong Global Performance

Achieved #1 Market share  
in 100% of countries/regions\*

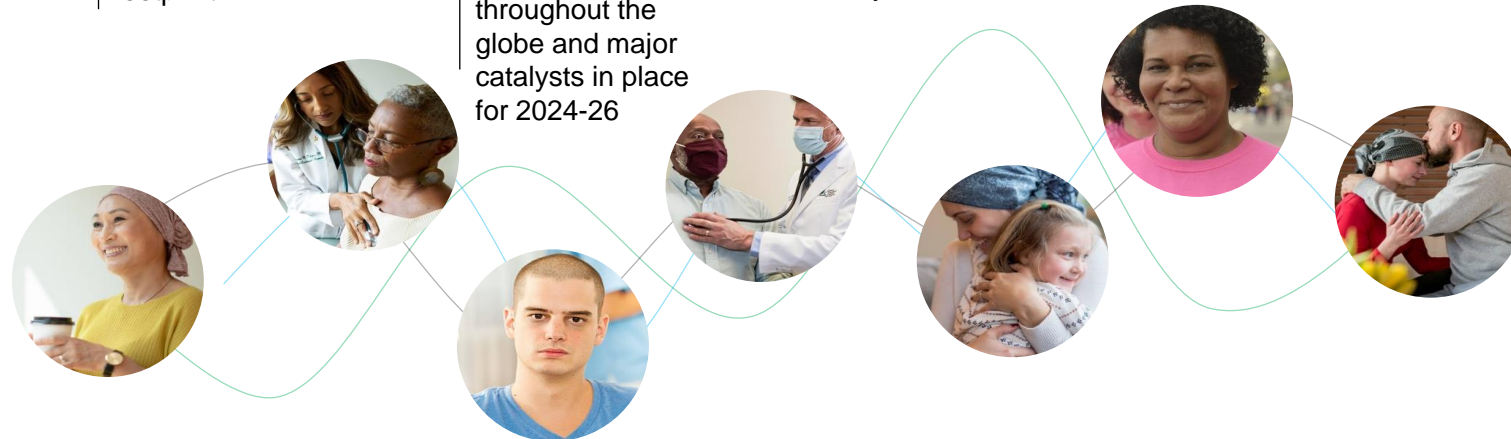
	<p>US APPROVAL: MAY 2022    EU Approval: JULY 2022</p> <p><b>2L+ HER2+ Metastatic Breast Cancer</b></p> <p>JP APPROVAL: NOV 2022</p>	
	<p>US APPROVAL: AUG 2022    EU Approval: JAN 2023</p> <p><b>2L+ HER2 low Metastatic Breast Cancer**</b></p> <p>JP APPROVAL: MAR 2023</p>	
	<p>US APPROVAL: AUG 2022    EU Approval: OCT 2023</p> <p><b>2L HER2 Mutant Metastatic NSCLC</b></p> <p>JP APPROVAL: AUG 2023</p>	
	<p>US APPROVAL: JAN 2021    EU Approval: DEC 2022</p> <p><b>2L+ HER2+ Metastatic Gastric Cancer***</b></p> <p>JP APPROVAL: SEP 2020</p>	

**>55**  
countries/  
regions  
Robust commercial footprint

**70%**  
revenue growth\*\*\*\*  
Accelerating momentum throughout the globe and major catalysts in place for 2024-26

**\$2.3B**  
in revenue delivered in CY 2023 with US and EU leading the way

More than  
**81K**  
patients across breast, lung, and gastric cancer



\* Fully launched    \*\* HER2 low metastatic breast cancer (post-chemo)    \*\*\* 3L HER2+ metastatic gastric cancer is approved in Japan. There is no current 2L approval in Japan for metastatic gastric cancer    \*\*\*\* year-over-year

NSCLC, non-small cell lung cancer

# All Four Regions Delivering:

## Global Net Sales have Exceeded 100 Bn JPY Per Quarter

Overall, global net sales in FY2023 Q3 was 102.6 Bn JPY; +12.0% sequential q-o-q growth driven by ASCA and Europe

US

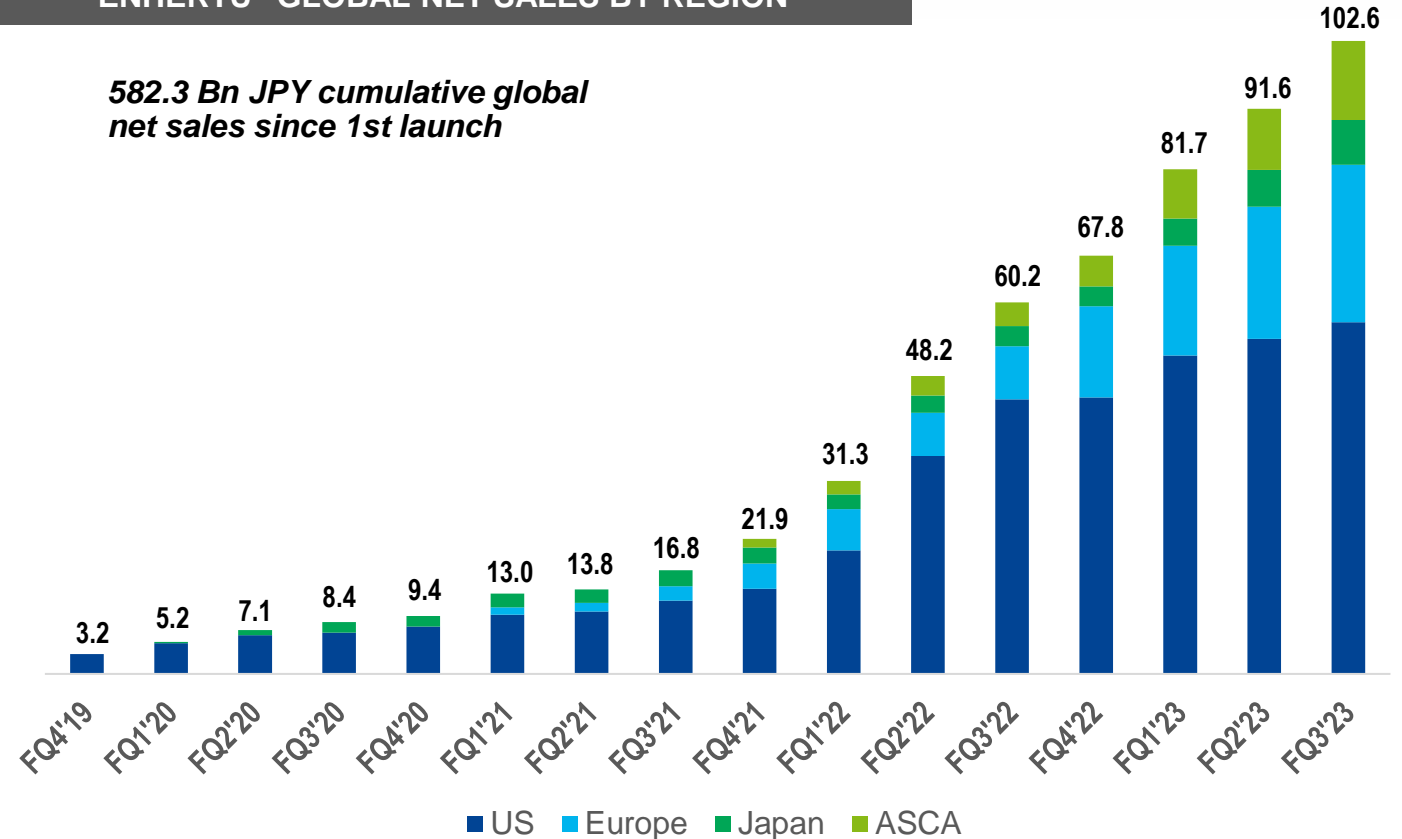
- In the US, FY2023 Q3: 57.0 Bn JPY  
+5.0% vs. prior quarter;  
+12.5 Bn JPY (+28.1%) vs. prior year

EU

- In the EU, FY2023 Q3: 25.5 Bn JPY  
+19.2% vs. prior quarter;  
+16.9 Bn JPY (+196.5%) vs. prior year

### ENHERTU® GLOBAL NET SALES BY REGION

582.3 Bn JPY cumulative global net sales since 1st launch



Growth rates were not calculated using constant exchange rates



# Growth Opportunities Remain in Current Indications, Including HER2+ mBC 2L

## HIGH ADOPTERS



- ENHERTU<sup>®</sup> is dominant market leader
- Oncologists rate ENHERTU<sup>®</sup> as most efficacious treatment option
- Real world experience matches the impressive clinical trial results
- Experience has strengthened oncology community's confidence in managing adverse events
- Oncologists report they expect to use more of ENHERTU<sup>®</sup> in future
- Access is supportive of appropriate use

UNITED STATES

FRANCE

ITALY

## GROWTH MODE



- ENHERTU<sup>®</sup> is market leader
- Majority of countries/regions are in earlier phase of product launch (usually due to timing of access)
- Early experiences are positive, and oncologists expect much greater use in future
- As experience builds, adoption will accelerate

JAPAN

GERMANY

SPAIN

UNITED KINGDOM

## RECENT OR NOT "LAUNCHED"



- Securing access is necessary and can be slower in some countries/regions
- Oncologists in these countries/regions are eagerly awaiting ENHERTU<sup>®</sup> availability
- Once access is secured, adoption will increase

OTHERS

# Growth Opportunities Remain in Current Indications, Including HER2 low mBC (post-chemo)

## HIGH ADOPTERS



- Use Post ET, CDK4/6i and chemotherapy utilization is standard of care and growing
- Patients routinely receive two lines plus of ET therapy prior to moving to chemotherapy
- Oncologists perceive 1st line chemotherapy to be sub-optimal and are eager to see the results of DESTINY-Breast06

UNITED STATES

## GROWTH MODE



- More recent access obtainment and hence early in the adoption curve
- Oncologists cycle through multiple lines of ET, though less than in the US
- Early positive experiences and expectations of greater use in future

JAPAN

FRANCE

GERMANY

## RECENT OR NOT “LAUNCHED”



- Securing access is necessary and can be slower in some countries/regions
- Confident in our ability to secure appropriate access in 2024
- Oncologists in these countries/regions are eagerly awaiting ENHERTU<sup>®</sup> availability
- Once access is secured, adoption will increase

ITALY

SPAIN

UNITED KINGDOM

# ENHERTU<sup>®</sup> Has Multiple Potential Growth Catalysts

## Seven Potential New ENHERTU<sup>®</sup> Growth Catalysts in the Next Three Years

FY2024		FY2025		FY2026	
INDICATION	TRIAL	INDICATION	TRIAL	INDICATION	TRIAL
Pan-tumor indication*	DESTINY-PanTumor02 etc.	HER2 low/HR+ BC (chemo naïve)	DESTINY-Breast06	HER2+ BC High Risk Adjuvant	DESTINY-Breast05
		HER2+ mBC 1L	DESTINY-Breast09		
		HER2mut NSCLC 1L	DESTINY-Lung04		
		HER2+ BC Neoadjuvant	DESTINY-Breast11		
		HER2+ mGC 2L**	DESTINY-Gastric04		

\*US PDUFA date, May 30, 2024

\*\*For confirmatory approval in Europe and approvals in Japan and China

BC, breast cancer; mBC, metastatic breast cancer; GC, gastric cancer; HR: hormone receptor; mGC, metastatic gastric cancer; NSCLC, non-small cell lung cancer

# If Approved, New Indications for ENHERTU® Will More Than Double the Patients Eligible for ENHERTU® in 2026

INDICATION	TRIAL	CURRENT STANDARD OF CARE	OPPORTUNITY IN MAJOR MARKETS****
Pan-tumor	DESTINY-PanTumor02	Varies by tumor	~ 10k
HR+/HER2 low BC (chemo naïve)	DESTINY-Breast06	chemotherapy	~ 18k
HER2+ mBC 1L	DESTINY-Breast09	THP**	~ 8k
HER2+ BC High Risk Adjuvant	DESTINY-Breast05	Kadcyla Trastuzumab + pertuzumab ± chemotherapy	~ 10k
HER2mut NSCLC 1L	DESTINY-Lung04	IO combo IO mono IO + chemotherapy	~ 2k
HER2+ BC Neoadjuvant	DESTINY-Breast11	TCHP***	~ 27k
HER2+ mGC 2L	DESTINY-Gastric04*	ENHERTU® Ramucirumab ± chemotherapy IO	~ 3k

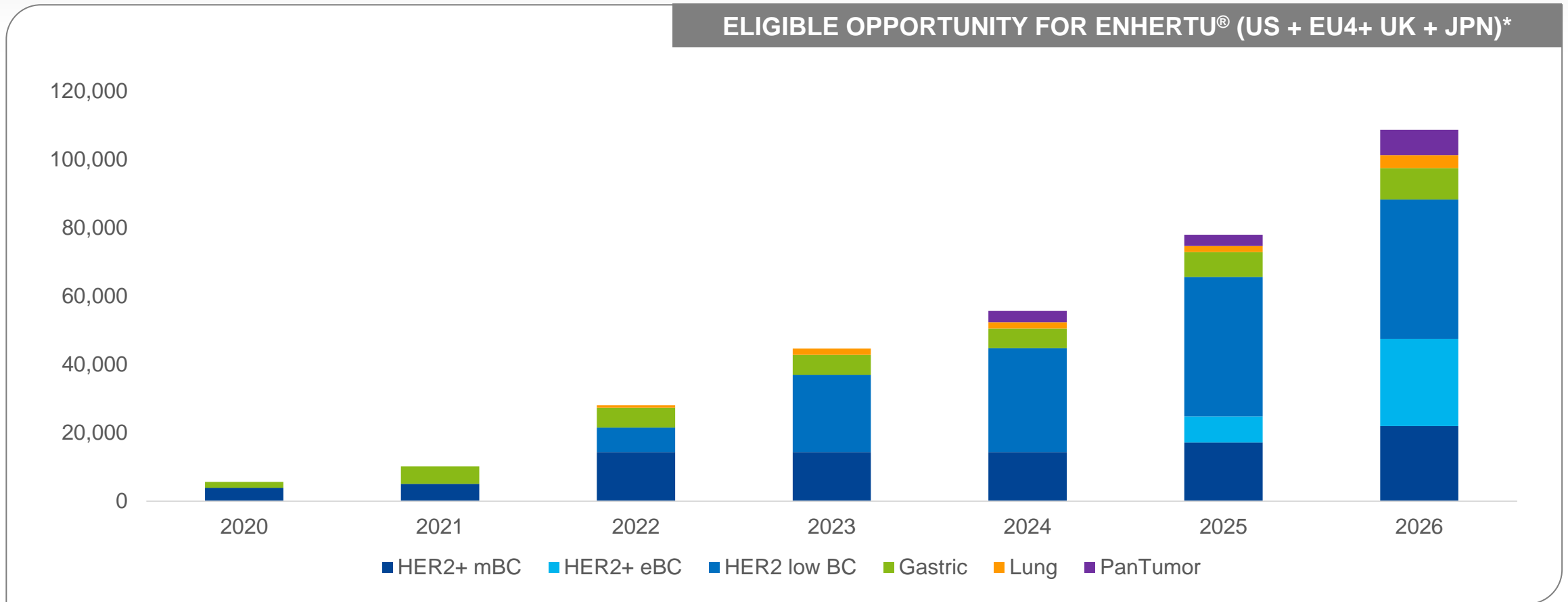
\* For confirmatory approval in Europe and approvals in Japan and China

\*\*THP, docetaxel + trastuzumab + pertuzumab

\*\*\*TCHP, carboplatin + docetaxel + trastuzumab + pertuzumab; IO, immuno-oncology therapy

\*\*\*\* US, France, Germany, Italy, Spain, UK, Japan

# The Eligible Patient Opportunity for ENHERTU® Will Grow to > 100k in 2026



\* Calendar Year

BC, breast cancer; eBC, early breast cancer; mBC, metastatic breast cancer



# Yields Thirteen New Portfolio Growth Catalysts in the Next Three Years

ENHERTU®

HER3-DXd

Dato-DXd

	FY2024		FY2025		FY2026 “Cure is our Cause”	
ENHERTU®	<b>INDICATION</b>	<b>TRIAL</b>	<b>INDICATION</b>	<b>TRIAL</b>	<b>INDICATION</b>	<b>TRIAL</b>
	Pan-tumor indication*	DESTINY-PanTumor02 etc.	HR+ /HER2 low BC (chemo naïve )	DESTINY-Breast06	HER2+ High Risk Adjuvant BC	DESTINY-Breast05
			HER2+ 1L mBC	DESTINY-Breast09		
			HER2mut 1L NSCLC	DESTINY-Lung04		
			HER2+ Neoadjuvant BC	DESTINY-Breast11		
		HER2+ 2L mGC****	DESTINY-Gastric04			
HER3-DXd	<b>INDICATION</b>	<b>TRIAL</b>	<b>INDICATION</b>	<b>TRIAL</b>		
	EGFRm NSCLC 3L**	HERTHENA-Lung01	EGFRm NSCLC 2L	HERTHENA-Lung02		
Dato-DXd	<b>INDICATION</b>	<b>TRIAL</b>	<b>INDICATION</b>	<b>TRIAL</b>		
	NSQ NSCLC 2L***	TROPION-Lung01	HR+ /HER2 low or negative mBC 2/3L	TROPION-Breast01		
			TNBC, PD-1/PD-L1 ineligible 1L	TROPION-Breast02		
		NSCLC w/o AGA, PD-L1 ≥ 50% 1L	TROPION-Lung08			

\* US PDUFA date, May 30, 2024

\*\* US PDUFA date, June 26, 2024

\*\*\* US PDUFA date, December 20, 2024

\*\*\*\* For confirmatory approval in Europe and approvals in Japan and China

AGA, actionable genomic alterations, BC, breast cancer; GC, gastric cancer, HR, hormone receptor; NSCLC, non-small cell lung cancer; NSQ, non-squamous; TNBC, triple negative breast cancer

# HER3-DXd: HERTHENA-Lung01 Opportunity



- Significant unmet need remains as current 3L treatments have limited efficacy
- Several trials have failed to significantly improve outcomes

Confirmed ORR

29.8%

Median PFS

5.5  
months

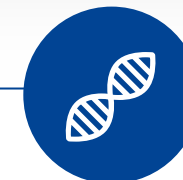
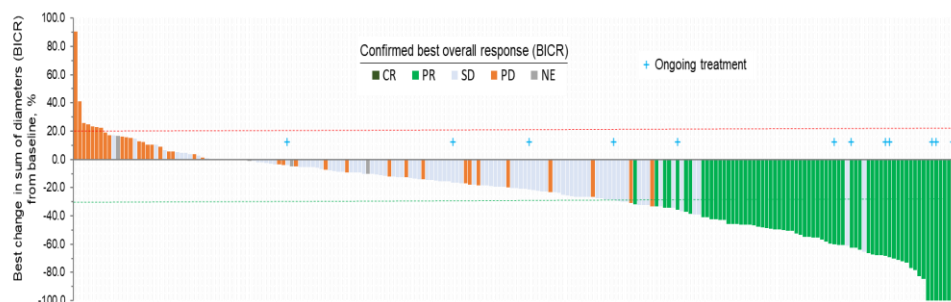
DCR

73.8%

Median OS

11.9  
months

HER3-DXd 5.6 mg/kg (N=225)<sup>a</sup>



- First-in-class HER3-directed ADC with no biomarker or requirement for HER3 IHC testing
- Clinically meaningful responses and strong survival data
- Manageable safety profile
- Major market patient opportunity of ~ 10k

BICR, blinded independent central review; CR, complete response; HER, human epidermal growth factor receptor; IHC, immunohistochemistry; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease; TKI, tyrosine kinase inhibitor; ORR, objective response rate; PFS, progression-free survival; DCR = disease control rate; OS = overall survival

<sup>a</sup> 210 patients had evaluable target lesion measurements at both baseline and post baseline and are included.

Snapshot data cutoff, 18 May 2023.

Median study follow-up, 18.9 (range, 14.9-27.5) months.

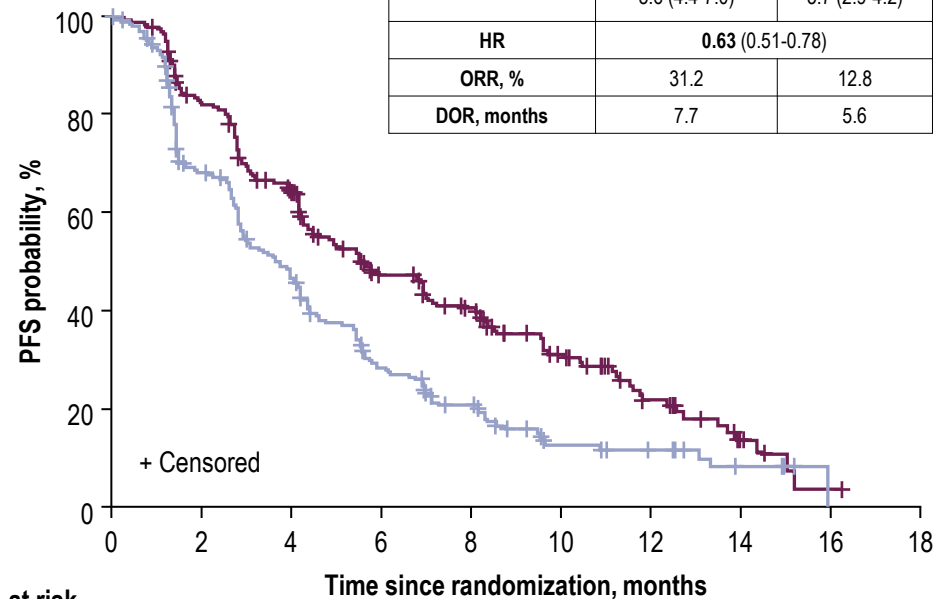
# Dato-DXd: TROPION-Lung01 Opportunity



- Significant unmet patient need in 2L+ non-squamous NSCLC as current standard-of-care chemotherapy in this setting is associated with a modest benefit and substantial toxicity
- Since 2021, there have been seven failed studies vs. docetaxel in this setting

## Clinically meaningful benefit in NSQ PFS, with positive OS trend at interim analysis

	Dato-DXd	Docetaxel
Median PFS (95% CI), months	5.6 (4.4-7.0)	3.7 (2.9-4.2)
HR	0.63 (0.51-0.78)	
ORR, %	31.2	12.8
DOR, months	7.7	5.6



- Dato-DXd is the first ADC to demonstrate a statistically significant improvement in PFS over docetaxel\*
- PFS benefit was primarily driven by patients with non-squamous histology
- Fewer grade  $\geq 3$  TRAEs vs. docetaxel and no new safety signals were observed with Dato-DXd
- Grade  $\geq 3$  ILD was seen, highlighting the need for careful monitoring and adherence to ILD management guidelines
- The interim OS findings favor Dato-DXd, and the trial is continuing to final analysis
- Major market opportunity of ~ 80k

\* In patients with previously treated, locally advanced or metastatic NSCLC



# Dato-DXd: TROPION-Breast01 Opportunity



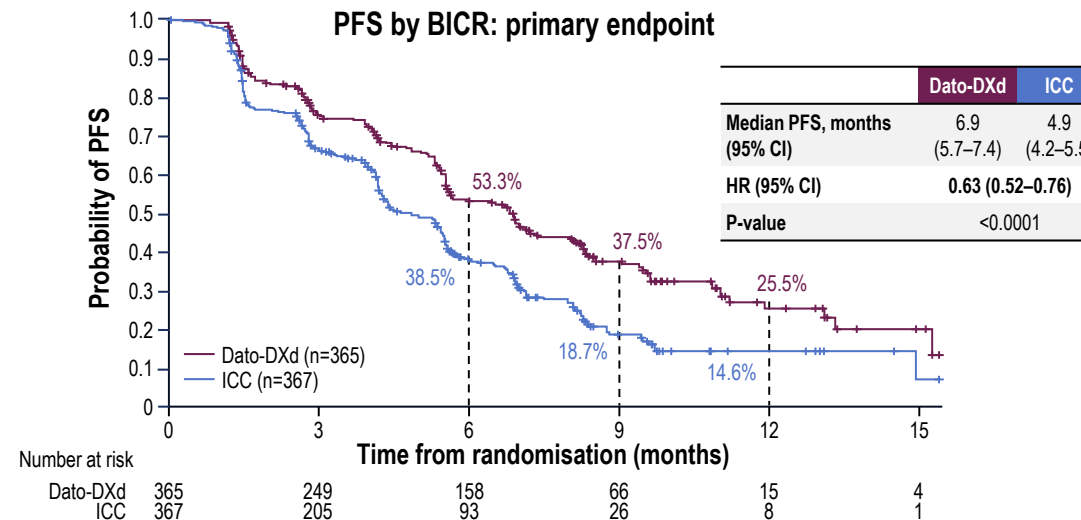
- There remains unmet need in HR+ / HER2 low or negative breast cancer for patients who progress on and are not suitable for endocrine therapy and were previously treated with 1-2 prior line(s) of chemotherapy
- Marketed TROP2 ADC indicated for later line patients ( $\geq$  two prior lines of chemotherapy), with unmet needs in earlier lines remaining

## TROPION-Breast01 Study

- The dual primary endpoints are PFS and OS
- TLR was obtained in Sep 2023



- Statistically significant and clinically meaningful efficacy vs. chemotherapy
- Convenient Q3W dosing schedule
- Manageable safety profile
- Major market patient opportunity of ~ 55k



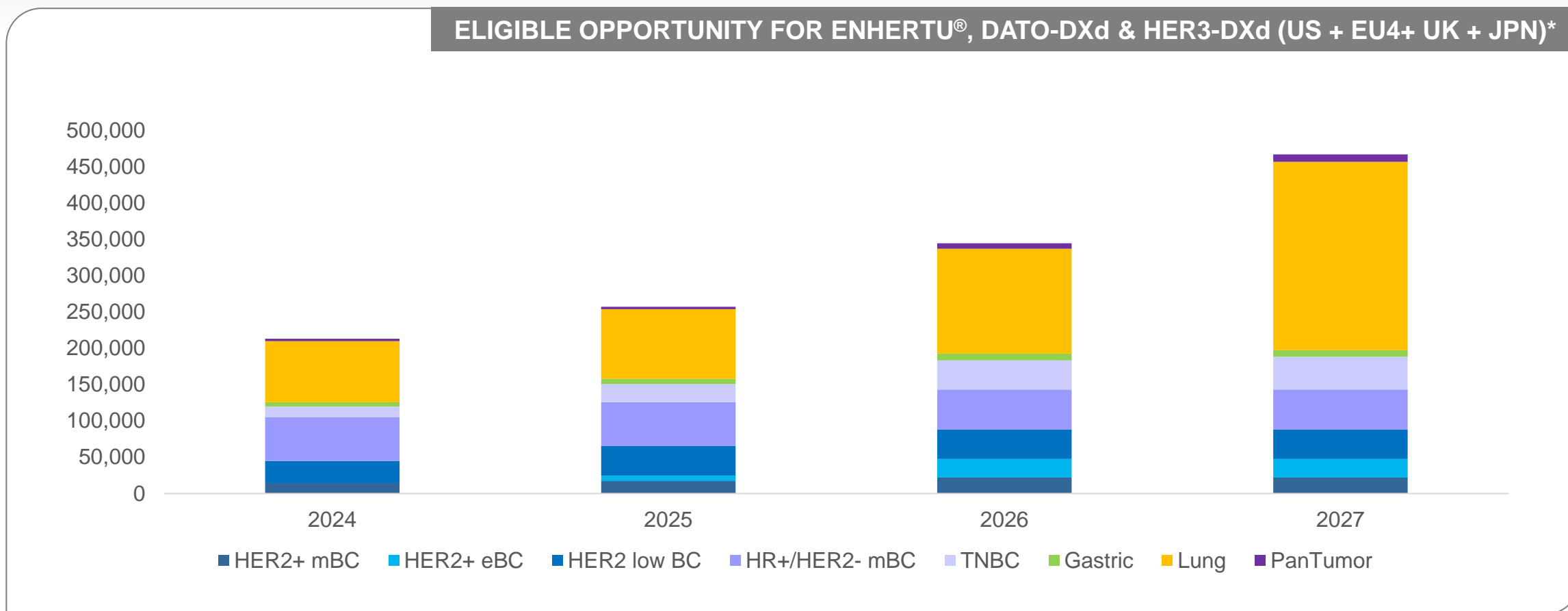
# Our Expanding Portfolio Will Dramatically Increase our Opportunity to Help Patients with Cancer

ASSET	TRIAL	INDICATION(S)	CURRENT STANDARD OF CARE	OPPORTUNITY IN MAJOR MARKETS*
Dato-DXd	TROPION-Lung01	NSQ NSCLC 2L	docetaxel	~ 80k
	TROPION-Breast01	HR+/HER2 low or negative mBC 2/3L	chemotherapy (eribulin, capecitabine, vinorelbine)	~ 55k
HER3-DXd	HERTHENA-Lung01	EGFRm NSCLC 3L	Platinum-based chemotherapy	~ 10k
I-DXd	IDeate-Lung01 IDeate-Lung02	SCLC 2L+	lurbinectedin	~ 13k
DS-6000 (R-DXd)	REJOICE-Ovarian01	PROC 2L	mirvetuximab soravtansine (FR $\alpha$ positive)	~ 8k

\* US, France, Germany, Italy, Spain, UK, Japan

FR, folate receptor; HR, hormone receptor; mBC, metastatic breast cancer; NSCLC, non-small cell lung cancer; NSQ, non-squamous; PROC, platinum-resistant ovarian cancer; SCLC, small cell lung cancer

# The Eligible Patient Opportunity for ENHERTU<sup>®</sup>, Dato-DXd and HER3-DXd Approaches Nearly 500k in the Major Markets



\* Calendar Year

eBC, early breast cancer; HR, hormone receptor; mBC, metastatic breast cancer; TNBC, triple-negative breast cancer

# I-DXd and DS-6000 (R-DXd) are Expected to be the Fourth and Fifth DXd ADCs to Launch in the Market

## I-DXd OPPORTUNITY

- SCLC is an area with significant unmet need with poor patient prognosis, limited therapy advancements in 2L+ SCLC and opportunities to improve survival benefit in 1L
- The current market is fragmented; however, platinum re-challenge is the leading regimen in platinum sensitive patients
- I-DXd has highly encouraging data to accelerate 2L+ development. There is an opportunity to pursue earlier lines of therapy with combination strategies
- I-DXd has potential in multiple tumor types that have broad expression of B7-H3

## DS-6000 (R-DXd) OPPORTUNITY

- Despite treatment advances, an unmet need remains in 2L+ platinum-resistant ovarian cancer as efficacy declines steeply following platinum failure
- The availability of mirvetuximab soravtansine has led to an evolution in the treatment of PROC but there is durable unmet need
- There is an opportunity to expand DS-6000 (R-DXd) by moving to earlier lines of therapy including 2L platinum-sensitive ovarian cancer and 1L ovarian cancer settings
- DS-6000 (R-DXd) has potential in multiple tumor types that express CDH6

# By 2030, Daiichi Sankyo Could Have Five Marketed ADCs in Over 30 Indications, Serving Nearly 400k Patients

## 2030 Aspiration:

### 5 Approved ADCs

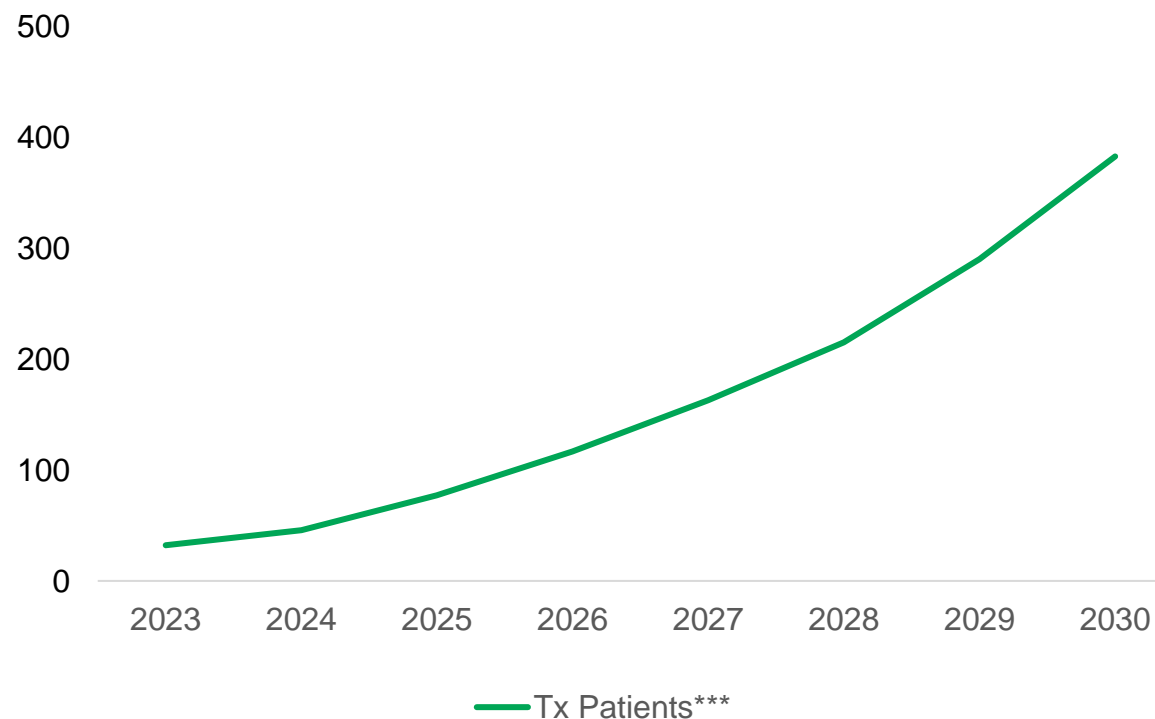
- ENHERTU®
- Dato-DXd
- HER3-DXd
- I-DXd
- DS-6000 (R-DXd)

## 2030 Aspiration:

### >30 Approved Indications\*

- Early-stage BC
- Metastatic BC
- NSCLC
- SCLC
- Gastric cancer
- Ovarian cancer
- Other

## NEW PATIENTS (000s)\*\*

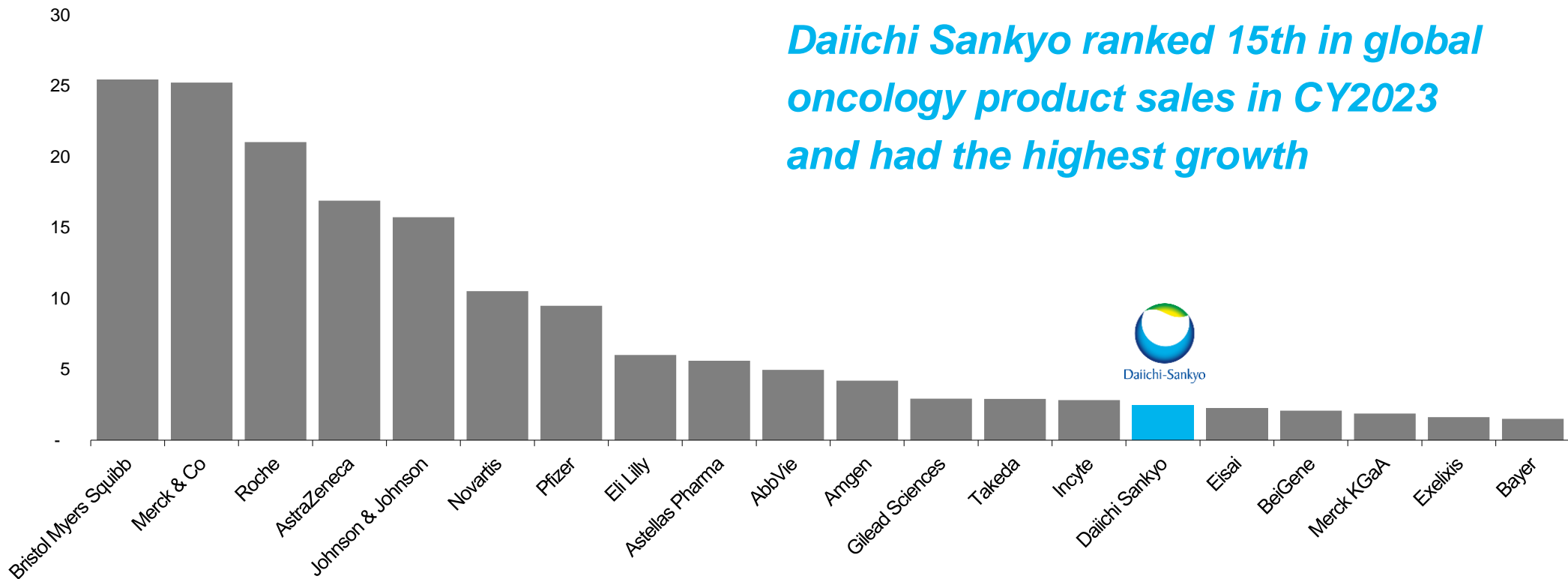


\* Risk-Adjusted \*\* Calendar Year \*\*\* Daiichi Sankyo therapy-treated patients

BC, breast cancer; NSCLC, non-small cell lung cancer; SCLC, small cell lung cancer

# Progressing Toward its “Top Ten” Goal

GLOBAL ONCOLOGY PRODUCT SALES (\$B)



Source: EvaluatePharma, accessed March 11, 2024

# DAIICHI SANKYO'S ONCOLOGY PORTFOLIO HAD THE Highest Growth in CY 2023

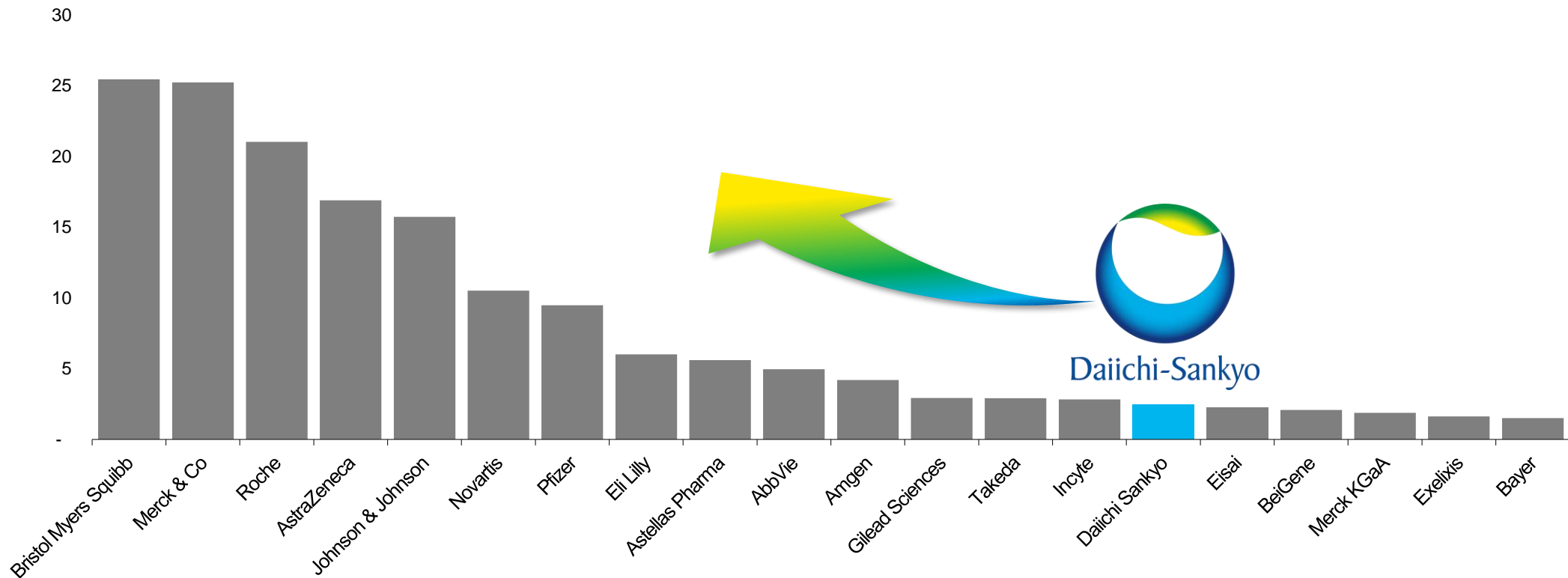


Source: EvaluatePharma, accessed March 11, 2024

Size of bubble is reflective of market cap of firm as of March 11, 2024

# We Will Reach Our Goal and Exceed Our Commitment

## GLOBAL ONCOLOGY PRODUCT SALES (\$B)



Source: EvaluatePharma, accessed March 11, 2024



## Contact address regarding this material

**Daiichi Sankyo Co., Ltd.**

Corporate Communications Department

TEL: +81-3-6225-1125

Email: [DaiichiSankyoIR@daiichisankyo.co.jp](mailto:DaiichiSankyoIR@daiichisankyo.co.jp)